

## PATENT COOPERATION TREATY

## PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY  
(Chapter II of the Patent Cooperation Treaty)

19 AUG 2004

PCT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference <b>YCT-860</b>	FOR FURTHER ACTION See Form PCT/IPEA/416	
International application No. <b>PCT/JP 03 / 10309</b>	International filing date (day/month/year) <b>13.08.2003</b>	Priority date (day/month/year) <b>14.08.2002</b>
International Patent Classification (IPC) or national classification and IPC Int.Cl. <b>C12N 15/54, 9/10, 5/10, C12Q 1/68, C07K 16/40, G01N 33/566, 33/574//C12P 21/08</b>		
Applicant <b>NATIONAL INSTITUTE OF ADVANCED INDUSTRIAL SCIENCE AND TECHNOLOGY</b>		

<p>1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>5</u> sheets, including this cover sheet.</p> <p>3. This report is also accompanied by ANNEXES, comprising:</p> <p>a. <input type="checkbox"/> a total of _____ sheets, as follows:</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis of this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions).</p> <p style="margin-left: 40px;"><input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box.</p> <p>b. <input checked="" type="checkbox"/> a total of (indicate type and number of electronic carrier(s)) <u>1 FD</u>, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).</p>	
<p>4. This report contains indications relating to the following items:</p> <p><input checked="" type="checkbox"/> Box No. I Basis of the report</p> <p><input type="checkbox"/> Box No. II Priority</p> <p><input checked="" type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</p> <p><input type="checkbox"/> Box No. IV Lack of unity of invention</p> <p><input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</p> <p><input type="checkbox"/> Box No. VI Certain documents cited</p> <p><input type="checkbox"/> Box No. VII Certain defects in the international application</p> <p><input type="checkbox"/> Box No. VIII Certain observations on the international application</p>	

Date of submission of the demand <b>11.03.2004</b>	Date of completion of this report <b>28.07.2004</b>	
Name and mailing address of the IPEA/JP <b>Japan Patent Office</b> <b>3-4-3, Kasumigaseki, Chiyoda-ku, Tokyo 100-8915, Japan</b>	Authorized officer <b>YUTAKA NIIDOME</b>	4B 9639
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## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP 03 / 10309

## Box No. I Basis of the report

1. With regard to the language, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.

- ☐ This report is based on translations from the original language into the following language \_\_\_\_\_, which is the language of a translation furnished for the purposes of:
- ☐ international search (under Rules 12.3 and 23.1(b))
  - ☐ publication of the international application (under Rule 12.4)
  - ☐ international preliminary examination (under Rules 55.2 and/or 55.3)

2. With regard to the elements of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:

- ☒ the international application as originally filed/furnished
- ☐ the description:  
pages \_\_\_\_\_ as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the claims:  
pages \_\_\_\_\_ as originally filed/furnished  
pages\* \_\_\_\_\_ as amended (together with any statement) under Article 19  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☐ the drawings:  
pages \_\_\_\_\_ as originally filed/furnished  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_  
pages\* \_\_\_\_\_ received by this Authority on \_\_\_\_\_
- ☒ a sequence listing and/or any related table(s) - see Supplemental Box Relating to Sequence Listing.

3. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).

- ☐ the description, pages \_\_\_\_\_
- ☐ the claims, Nos. \_\_\_\_\_
- ☐ the drawings, sheets/figs \_\_\_\_\_
- ☐ the sequence listing (specify): \_\_\_\_\_
- ☐ any table(s) related to sequence listing (specify): \_\_\_\_\_

\* If item 4 applies, some or all of those sheets may be marked "superseded."

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

International application No.

PCT/JP03 / 10309

## Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application
- ☒ claims Nos. 1-19 (partially) and 20-23

because:

- ☒ the said international application, or the said claims Nos. 20-23  
relate to the following subject matter which does not require an international preliminary examination (*specify*):

Claims 20-23 are directed to a method for treatment of the human body by therapy, for which the International Preliminary Examining Authority is not required, under PCT Article 34 (4) (a) (i) and Regulation 67.1(iv), to carry out an international preliminary examination.

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. \_\_\_\_\_ are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. \_\_\_\_\_ are so inadequately supported by the description that no meaningful opinion could be formed.
- ☒ no international search report has been established for said claims Nos. 1-19 (partially), 20-23
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- |                            |                          |                                   |
|----------------------------|--------------------------|-----------------------------------|
| the written form           | <input type="checkbox"/> | has not been furnished            |
|                            | <input type="checkbox"/> | does not comply with the standard |
| the computer readable form | <input type="checkbox"/> | has not been furnished            |
|                            | <input type="checkbox"/> | does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing do not comply with the technical requirements provided for in Annex C-bis of the Administrative Instructions in that the computer readable form:
- |                          |   |
|--------------------------|---|
| <input type="checkbox"/> | has not been furnished                          |
| <input type="checkbox"/> | does not comply with the technical requirements |
- ☐ See Supplemental Box for further details.

**Box No. V** Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**1. Statement**

Novelty (N)	Claims	<u>1-19 (partially)</u>	YES
	Claims	<u></u>	NO
Inventive step (IS)	Claims	<u>1-14, 16-19 (partially)</u>	YES
	Claims	<u>15 (partially)</u>	NO
Industrial applicability (IA)	Claims	<u>1-19 (partially)</u>	YES
	Claims	<u></u>	NO

**2. Citations and explanations (Rule 70.7)**

**D1: WO 01/53524 A2 (THE NOTTINGHAM TRENT UNIVERSITY), 2001.07.26**

**1. Concerning claim 15:**

The most relevant document cited in the international search report is D1.

D1 discloses a nucleic acid defined by SEQ.ID. 25 which encodes an antigen expressed in higher than normal concentrations in cancer cells (claim 1).

D1 further discloses nucleic acid probes comprising at least 15 nucleotides capable of specifically binding to the said nucleic acid.

Since SEQ.ID. 25 includes the full sequence of SEQ.ID. 25 in the present invention, which can also be used as a probe to discover cancer cells, it would be obvious to the skilled artisan to create a nucleic acid probe consisting the same sequence as SEQ.ID. 25 in the present application from SEQ.ID. 25 in D1.

Thus, claim 15 in the present application is considered obvious from D1.

**2. Concerning claims 1-14, 16-19:**

The subject matter of claims 1-14, 16-19 are neither disclosed or suggested in D1. Novelty and inventive step are acknowledged for these claims.

The subject matter of claims 1-19 are considered to have industrial applicability.

## Supplemental Box Relating to Sequence Listing

## Continuation of Box No. I, item 2:

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this report was established on the basis of:
  - a. type of material
    - ☒ a sequence listing
    - ☐ table(s) related to the sequence listing
  - b. format of material
    - ☐ in written format
    - ☒ in computer readable form
  - c. time of filing/furnishing
    - ☐ contained in the international application as filed
    - ☒ filed together with the international application in computer readable form
    - ☐ furnished subsequently to this Authority for the purposes of search and/or examination
    - ☐ received by this Authority as an amendment\* on \_\_\_\_\_
2. ☒ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments:

\* If item 4 in Box No. I applies, the replacement listing and/or table(s) related thereto may be marked "superseded"